The Vaccine Adverse Event Reporting System

What is VAERS?

The National Childhood Vaccine Injury Act (NCVIA) of 1986 mandated the reporting of certain adverse events following vaccination to help ensure the safety of vaccines distributed in the United States. This Act led to the establishment of the Vaccine Adverse Event Reporting System (VAERS) in November 1990 by the Department of Health and Human Services. VAERS provides a database management system for the collection and analysis of data from reports of adverse events following vaccination. VAERS is operated jointly by the Centers for Disease Control and Prevention (CDC)and the Food and Drug Administration (FDA). VAERS currently receives approximately 800-1000 reports each month.

Who can report to VAERS?

Any one can report to VAERS. VAERS reports are usually submitted by health care providers, vaccine manufacturers, and vaccine recipients (or their parents/guardians). Patients, parents, and guardians are encouraged to seek the help of a health-care professional in reporting to VAERS.

Why should I report to VAERS?

Registries of disease or injury work best when reporting is complete. Complete reporting of post-vaccination events supplies public health professionals with the information they need to ensure the safest strategies of vaccine administration.

Does my reporting injuries (or deaths) to VAERS affect personal liability?

No. The National Childhood Vaccine Injury Act of 1986 provides liability protection through the Vaccine Injury Compensation Program. In light of this protection, practitioner liability is unaffected by the VAERS reporting requirement.

What events should be reported to VAERS?

Although NCVIA only requires reporting of the post-vaccination adverse events mentioned in the Reportable Events Table (www.fda.gov/cber/vaers/eventtab.htm)**, VAERS encourages all reporting of any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States. On average, about 17% of the reports reflect adverse events resulting in life-threatening illness, hospitalization, permanent disability, extended hospital stay or death. The remaining 83% of the reports primarily describe events such as fever, local reactions transient crying or mild irritability, and other less serious experiences.**

The *Reportable Events Table* specifically outlines the reportable post-vaccination events and the time frames in which they must occur in order to qualify as being reportable. A copy of the Table can be obtained by calling 1-800-822-7967.

The NCVIA requires the following events be reported:

Any event set forth in the *Reportable Events Table* that occurs within the time period specified.

Any event listed in the manufacturer's package insert as a contraindication to subsequent doses of the vaccine.

How are VAERS reports analyzed?

Both the CDC and the FDA review data reported to VAERS. The CDC focuses on collective reports, attempting to detect unusual epidemiologic trends and associations. The FDA reviews individual reports, assessing whether a reported event is adequately reflected in product labeling, and also closely monitors reporting trends for individual vaccine manufacturers and vaccine lots.

Safety surveillance includes the analysis of reports by individual epidemiologists, and weekly review meetings of serious VAERS reports to detect potential risks which require further investigation.

Can information reported to VAERS cause a recall of a vaccine?

The FDA has the authority to recall a vaccine from use in the United States if they feel it represents a risk to the American public. VAERS reports may signal that there is the potential for a safety risk, which would prompt a wider evaluation of the safety of the vaccine lot. If the evaluation confirms a risk, the batch can be recalled.

Over the last 10 years, there have been only three vaccine recalls. One batch of vaccine was recalled after the FDA detected impurities in the vaccine; another was mislabeled. The third batch was recalled because an FDA inspection found substandard conditions at the production plant which had the potential to produce a substandard batch.

In the winter of 1996-97, a pharmaceutical company voluntarily withdrew a vaccine from distribution because it did not retain its protective effect long enough after manufacture to meet Federal standards. This vaccine was not a safety threat, but did not work well enough to protect people from getting the disease it was designed to protect them from.

Are all events reported to VAERS caused by vaccinations?

Again, VAERS accepts all reports of adverse events following vaccination, so not all events reported to VAERS are caused by vaccines. In fact, limitations such as differential reporting rates, simultaneous administration of different vaccine antigens, temporal reporting bias and lack of background vaccination rate data generally prevent the determination of vaccine-event causal associations using VAERS data. Without fully understanding its limitations, results from VAERS can easily be misinterpreted.